

# Exhibit G

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2  
3 IN RE: :SUPERIOR COURT OF  
PELVIC MESH/GYNECARE :NEW JERSEY  
4 LITIGATION :LAW DIVISION -  
:ATLANTIC COUNTY  
5 :  
:MASTER CASE 6341-10  
6 :  
:CASE NO. 291 CT

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF  
CONFIDENTIALITY

September 13, 2012

Volume II of the transcript of the  
Deposition of CHARLOTTE OWENS, M.D., called for  
Videotaped Examination in the above-captioned  
matter, said deposition taken pursuant to  
Superior Court Rules of Practice and Procedure,  
by and before JoRita B. Meyer, a Certified  
Realtime Reporter, Registered Merit Reporter,  
and Certified Court Reporter for the State of  
Georgia, at the offices of Troutman Sanders,  
600 Peachtree Street Northeast, Atlanta,  
Georgia, commencing at 9:11 a.m.

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1 A. Correct.

2 Q. And it says the potential effect of  
3 that is damage to the cannula and the potential  
4 hazard what could occur would be tissue damage,  
5 correct?

6 A. Correct.

7 Q. And the potential harm that could  
8 result here is described as bleeding, correct?

9 A. Correct.

10 Q. And you understood that through your  
11 review of this -- rephrase.

12 And you understood that it was  
13 required that you capture all of the different  
14 failure modes, all the things that could go  
15 wrong in the procedure, even if the doctor was  
16 properly trained and following the proper  
17 procedure, and the effects of those failure  
18 modes, the hazards that could occur, and the  
19 resulting harms, and you were supposed to  
20 capture all of them, correct?

21 A. Yes, all that we could conceive of,  
22 yes.

23 Q. Now, one of the things that could  
24 happen is during the passage of the guides, is  
25 the pudendal nerve could be injured, correct?

1 specifically mentioned in the document.

2 BY MR. SLATER:

3 Q. And therefore, none of them are  
4 specifically scored, correct?

5 A. They would have been included in  
6 things other than the terms that you mentioned.

7 Q. As the document appears and as it was  
8 specifically and carefully written by quality  
9 engineering, with your approval, those items do  
10 not appear and are not specifically scored,  
11 correct?

12 A. Those items are not specifically  
13 mentioned, no.

14 Q. All right. Now let's look at the  
15 dFMEA, which is Exhibit 629. You understood  
16 the purpose of the dFMEA, correct?

17 A. Yes.

18 Q. That's the Design Failure Modes and  
19 Effects Analysis, correct?

20 A. Yes.

21 Q. And what was the purpose of this  
22 analysis?

23 A. To review the potential risk  
24 associated with the design of the product.

25 Q. And when you say "associated with the

1 design of the product," that means that when  
2 the product is in a woman's body and the  
3 product was manufactured completely consistent  
4 with the specifications, these are the things  
5 that could go wrong and harm a patient,  
6 correct?

7 A. Correct.

8 Q. Let's look now at this dFMEA, and  
9 let's look at page -- looking at the Bates  
10 number 03573, the actual chart and grid.

11 And it indicates that you were one of  
12 the individuals who provided input as medical  
13 director, correct?

14 A. Yes.

15 Q. And again, as with the aFMEA, you had  
16 to sign off on the dFMEA in order for this gate  
17 to be surpassed so the product could move  
18 closer to Product Release Authorization and to  
19 be marketed to be put in women's bodies,  
20 correct?

21 A. Correct.

22 Q. And what this does is, in the chart,  
23 is the different components of the PROLIFT kit  
24 are each evaluated in terms of what harms they  
25 could cause if they were to fail, correct?